

## REMARKS

The Office Action mailed on May 22, 2009, has been reviewed and the comments of the Examiner carefully considered. Claims 1, 5-13 and 20 are pending and currently stand rejected. Claim 1 been amended. Support for these amendments may be found in the specification and for example, from lines 23-33 on page 11 and from line 1 on page 12 through line 2 on page 13. No new matter is believed to have been added by way of these amendments.

### **Examiner Comments Regarding Claims**

The Examiner took issue with claim 20 for use of the claim identifier “previously presented”. Applicants respectfully submit that this claim identifier is proper, as claim 20 is not newly added, but rather, was previously presented as a new claim.

The Examiner suggested edits to claim 1 with regard to the term “antioxidant dyestuff”. Applicants appreciate the Examiner’s suggestions, and note that these terms in the claim have been addressed in response to the indefiniteness rejection, as set forth below.

### **Rejections under 35 U.S.C. § 112, Second Paragraph (“Indefiniteness”)**

Claims 1, 5-13 and 20 were rejected as allegedly indefinite for the use of the claim terms “antioxidant dyestuff” and “antimicrobial”. While not in agreement with the Examiner’s basis for rejection, Applicants have amended claim 1 to recite that the antioxidant dyestuff is bound to the surface of the solid bioabsorbable substrate and allows sustained release of antioxidant effective amounts of the antimicrobial antioxidant dyestuff. Support for these amendments can be found throughout the specification, and for example, at lines 22-33 on page 11, and from line 1 on page 12 through line 2 on page 13.

Accordingly, because amended claim 1, and dependent claims 5-13 and 20 are not indefinite, Applicants respectfully request reconsideration and withdrawal of the rejection.

### **Rejections under 35 U.S.C. § 103(a)**

1. Claims 1, 5, 6 and 20 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Partain et al. (EP0368253) in view of Rosenthal et al. (US 5,565,210). It is the Examiner’s view that the combination of the cited patents would lead one of skill in the art to

arrive at claims 1, 5, 6 and 20, in their entirety. Applicants respectfully traverse the Examiner's rejection for the following reasons.

The test which must be met for a reference or a combination of references to establish obviousness has not been satisfied in the instant matter. The MPEP states, in relevant part, the proper test for obviousness:

Office policy is to follow *Graham v. John Deere Co.* in the consideration and determination of obviousness under 35 U.S.C. § 103 ...

[T]he four factual inquiries enunciated therein as a background for determining obviousness are as follows:

- (A) Determining the scope and contents of the prior art;
- (B) Ascertaining the differences between the prior art and the claims in issue;
- (C) Resolving the level of ordinary skill in the pertinent art; and
- (D) Evaluating evidence of secondary considerations. (MPEP § 2141).

When applying 35 U.S.C. § 103, the following tenets of patent law must be followed: 1) the claimed invention must be considered as a whole; 2) the references must be considered as a whole; 3) the references must be viewed without the benefit of impermissible hindsight vision afforded by the claimed invention; and 4) reasonable expectation of success is the standard with which obviousness is determined. MPEP § 2141 II. This test has not been satisfied here for any of the obviousness rejections.

As set forth by Applicants in the Response filed on April 1, 2009, there is no disclosure by Partain or Rosenthal of dyeing a bioabsorbable wound dressing material with an antioxidant dye in either Partain or Rosenthal. While the delivery system of Partain is disclosed to be able to contain a large number of pharmaceutical and therapeutic actives that can be applied topically, including acridine dyes, the term "dyed" as used in the instant claims refers to a solid material that has been surface-treated while in the solid state with a dye to bind the dye. Partain and Rosenthal do not teach such a composition. Partain and Rosenthal simply do not provide any teaching, suggestion or motivation to prepare such a material.

In fact, as pointed out by the Examiner in the current Office Action, Partain teaches the addition of a dyestuff to an aqueous solution for preparation of a final product. However, Applicants respectfully submit that the Examiner incorrectly equates this teaching with Applicants' presently-claimed invention. Again, the term "dyed" as used in the instant claims

refers to a solid material that has been surface-treated while in the solid state with a dye to bind the dye, and not the addition of a dyestuff to an aqueous solution, as suggested by the Examiner (See, e.g., the definition of the term “dyed” on page 4 of the specification).

Neither Partain nor Rosenthal teach a “dyed” composition. Instead, Partain, or the combination of Partain and Rosenthal, teaches a composition that may or may not include a dyestuff in an aqueous preparation that is subsequently dried down or solidified. Neither reference teaches that any of the materials in the mixtures are covalently modified by a dyestuff, and, in fact, Partain teaches that chitosan materials in the compositions of Partain are “salts” (i.e., ionic, and not covalent, preparations). Partain does not teach a covalent modification of the composition with a dyestuff. Moreover, Partain does not teach or even suggest the use of cellulose to prepare any type of composition. Partain teaches and exemplifies aminopolysaccharides such as chitosan.

MPEP § 2141.02(VI) requires that a prior art reference be taken as a whole, for all it fairly teaches. When Partain is taken as a whole, for all it fairly teaches, the skilled artisan would not find any teaching or suggestion in Partain to arrive at Applicants’ claimed invention. Furthermore, the evaluation of a prior art reference for purposes of patentability is supposed to be conducted from the point of view of the skilled artisan. A skilled artisan viewing Partain would not find any teaching or suggestion of a covalent modification of oxidized cellulose with a dyestuff, i.e., a dyeing of the cellulose.

Rosenthal does not cure the deficiencies of Partain. While Rosenthal may teach the use of an oxidized cellulose to make a bioabsorbable material, again, Rosenthal does not teach or suggest the dyeing of cellulose using a dyestuff. There is no teaching or suggestion in Rosenthal or in Partain to use the compositions of Rosenthal to prepare compositions according to Partain. Assuming, *arguendo*, that the skilled artisan viewing Partain would even think to use a saccharide other than chitosan, there is still no teaching, in either reference, as to how or why the skilled artisan would dye a composition as taught in Applicants’ present claims.

Neither Partain nor Rosenthal provides any teaching, suggestion or motivation to arrive at the presently-claimed invention, and therefore, the skilled artisan would not have any reasonable expectation of success in arriving at Applicants claimed invention without the use of improper hindsight reasoning. Consequently, because none of the rejected claims are obvious in view of Partain and Rosenthal as set forth above, Applicants respectfully request withdrawal of the

rejection of claim 1 under 35 U.S.C. § 103(a). Further, applicants submit that claims 5, 6 and 20 are thereby allowable as written as depending from an allowable independent claim.

2. Claims 1, 5-7, 13 and 20 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Partain and Rosenthal, further in view of Fowler et al. (US 5,667,501). It is the Examiner's view that the combination of the cited patents would lead one of skill in the art to arrive at claims 1, 5-7, 13 and 20, in their entirety. Applicants respectfully traverse the Examiner's rejection for the following reasons.

As set forth above, Partain and Rosenthal, taken together, do not render the claims obvious. Fowler does not correct this deficiency. Fowler does not teach a solid material that has been surface-treated while in the solid state with a dye to bind the dye. Fowler does not teach oxidized cellulose wherein an antioxidant dyestuff is covalently bound to the cellulose.

Because Partain, Rosenthal and Fowler, taken together, do not provide any teaching, suggestion or motivation to arrive at the presently-claimed invention, and therefore, the skilled artisan would not have any reasonable expectation of success in arriving at Applicants claimed invention without the use of improper hindsight reasoning. Consequently, because none of the rejected claims are obvious in view of Partain, Rosenthal and Fowler as set forth above, Applicants respectfully request withdrawal of the rejection of claim 1 under 35 U.S.C. § 103(a). Further, applicants submit that claims 5-7, 13 and 20 are thereby allowable as written as depending from an allowable independent claim.

3. Claims 1, 5-10 and 20 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Partain, Rosenthal, and Fowler, further in view of Nimrod (WO 87/05517). It is the Examiner's view that the combination of the cited patents would lead one of skill in the art to arrive at claims 1, 5-10 and 20, in their entirety. Applicants respectfully traverse the Examiner's rejection for the following reasons.

As set forth above, Partain, Rosenthal and Fowler, taken together, do not render the claims obvious. Nimrod does not correct this deficiency. Nimrod does not teach a solid material that has been surface-treated while in the solid state with a dye to bind the dye. Nimrod does not teach oxidized cellulose wherein an antioxidant dyestuff is covalently bound to the cellulose.

Because Partain, Rosenthal, Fowler, and Nimrod, taken together, do not provide any teaching, suggestion or motivation to arrive at the presently-claimed invention, and therefore, the skilled artisan would not have any reasonable expectation of success in arriving at Applicants claimed invention without the use of improper hindsight reasoning. Consequently, because none of the rejected claims are obvious in view of Partain, Rosenthal, Fowler, and Nimrod, as set forth above, Applicants respectfully request withdrawal of the rejection of claim 1 under 35 U.S.C. § 103(a). Further, applicants submit that claims 5-10 and 20 are thereby allowable as written as depending from an allowable independent claim.

4. Claims 1, 5-12 and 20 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Partain, Rosenthal, and Fowler, further in view of Gibbins (US 6,355,858). It is the Examiner's view that the combination of the cited patents would lead one of skill in the art to arrive at claims 1, 5-12 and 20, in their entirety. Applicants respectfully traverse the Examiner's rejection for the following reasons.

As set forth above, Partain, Rosenthal and Fowler, taken together, do not render the claims obvious. Gibbins does not correct this deficiency. Gibbins does not teach a solid material that has been surface-treated while in the solid state with a dye to bind the dye. Gibbins does not teach oxidized cellulose wherein an antioxidant dyestuff is covalently bound to the cellulose.

Because Partain, Rosenthal, Fowler, and Gibbins, taken together, do not provide any teaching, suggestion or motivation to arrive at the presently-claimed invention, and therefore, the skilled artisan would not have any reasonable expectation of success in arriving at Applicants claimed invention without the use of improper hindsight reasoning. Consequently, because none of the rejected claims are obvious in view of Partain, Rosenthal, Fowler, and Gibbins, as set forth above, Applicants respectfully request withdrawal of the rejection of claim 1 under 35 U.S.C. § 103(a). Further, applicants submit that claims 5-12 and 20 are thereby allowable as written as depending from an allowable independent claim.

### **Double Patenting Rejections**

1. Claims 1 and 8-10 were provisionally rejected on the ground of non-statutory obviousness-type double patenting as being unpatentable over claims 1-4, 7-13, 20 and 21 of copending application 10/579,850. Applicants respectfully submit that as the Examiner noted in

Section 8, page 6 of the Office Action, a Terminal Disclaimer was filed on April 1, 2009 and was accepted by the Patent Office on May 20, 2009. Therefore, Applicants respectfully submit that this rejection is moot.

2. Claims 1, 11-13 and 20 were provisionally rejected on the ground of non-statutory obviousness-type double patenting as being unpatentable over claims 1-18 of copending Application No. 10/579,897 in view of Partain. Applicants disagree with the grounds for rejection. However, at this time, Applicants respectfully request that the double patenting rejection be held in abeyance until claims in either this or the copending application are deemed to be allowable. At the time claims from one of the applications are found to be allowable, Applicants will consider the Examiner's rejection in view the final version of the allowable claims.

3. Claims 1-3 and 12 were provisionally rejected on the ground of non-statutory obviousness-type double patenting as being unpatentable over claims 1, 2, 4 and 13 of copending Application No. 10/608,553 in view of Partain. Applicants disagree with the grounds for rejection. The combination of references set forth by the Examiner does not yield a wound dressing material dyed with an antioxidant dyestuff wherein the dyestuff is bound to the surface of the bioabsorbable substrate and allows sustained release of the effective amounts of the antioxidant dyestuff.

The term "dyed" as used in the instant claims refers to a solid material that has been surface-treated while in the solid state with a dye to bind the dye. Partain does not teach such a composition, nor does Partain provide any teaching, suggestion or motivation to prepare such a material. Therefore, Partain cannot be used in conjunction with copending Application No. 10/608,553 to render the present claims obvious. Applicants respectfully request reconsideration and withdrawal of the rejection.

**Conclusion**

Applicants respectfully submit that the claims are in condition for allowance. An early Notice of Allowance is therefore earnestly solicited. Applicants invite the Examiner to contact the undersigned at (215) 963-5809 to clarify any unresolved issues raised by this response.


The Director is hereby authorized to charge/credit Deposit Account No. **50-0310** (Billing No. 101713-5030) for any other required fees, deficiencies or overpayments in connection with this Response.

Respectfully submitted,

**BREDA MARY CULLEN ET AL.**

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